Appendix 2

Documents for the Application for Drug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths

Technical document	According to regulations in appendixes 3						
Drug testing results/reports (Note4)		╳	╳		╳	╳	
Certificate of pharmaceutical product (CPP)		╳	○		╳	╳	
Report of stability study		○	○		○	○	
Validation report of critical manufacturing processes (two copies) (Note3)		○	○		○	○	
Validation report of analytical methods (two copies)		○	○		○	○	
Manufacturing and Control Standards report and the amount of all components in the batch record or batch records of the same lot as the finished product of the tentative production batch		○	○		○	○	
Specifications, testing methods and results for final products (Note7)		○	○		○	○	
Specifications, testing methods and results for excipients		○	○		○	○	
Technical documents of active pharmaceutical ingredients (Note5)		○	○		○	○	
Photocopy of GMP compliance certificate		○	○		○	○	
Formulation basis or study of formulation design (Note 2)		○	╳		○	╳	
CPP of source country (Note 1)		╳	○		╳	○	
Authorization		╳	○		╳	○	
License sticking form		○	○		○	○	
Label and package insert sticking form (two copies)		○	○		○	○	
Assurance statement (A & B)		○	○		○	○	
Application form (original copy and duplicate copy)		○	○		○	○	
Application fees		○	○		○	○	
Documents for (Note 6)	New Chemical Entity	Domestic products	Imported products	New administration route	Domestic products	Imported products	New Indication
	New Drugs						

×	×		×	×		×	×		×	×		×
×	×		×	×		×	×		×	×		×
○	○		○	○		○	○		○	○		○
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Domestic products	Imported products	New combination	Domestic products	Imported products	New dosage form	Domestic products	Imported products	New administration dose	Domestic products	Imported products	New unit strength	Domestic products
					New dosage form, new administration dose, new unit strength							

	Imported products	○	○	○	○	○	○	○	×	○	○	○	○	○	○	○	○	×	×	

Note:

○: submission required; ×: not required

1 If the source country's CPP does not contain the complete site address, a copy of the latest GMP site inspection report shall be provided. (If the incompleteness of CPP is of minor, i.e. lacking post code or district name, an explanation letter from the original manufacturer could be used as supplementary).

2 The submission of formulation basis is not required for preparations of new drugs, new dosage forms, new administration doses or new unit strengths that have been developed in Taiwan. However, the study of formulation design and related technical documents should be provided additionally.

3 If the product applied for registration is an imported sterile preparation, the report of critical manufacturing processes should state the part of sterilization validation.

4 According to Article 24 Paragraph 2, except for those being requested to have physical testing on the product by the central competent health authority as drug testing being necessary, the assessment of quality can be performed through dossier review instead of physical sample testing.

5 Not applicable for technical documents of those active pharmaceutical ingredients can be substituted by other dossier as announced by the central competent health authority.

6 Application dossiers shall be submitted according to the Common Technical Document (CTD) format.

7 Applications for the registration of pharmaceutical products with hard capsules, one of the following documents shall be provided for its review:

(1) For using domestic manufacturing hard capsules, the license number of the hard capsule shall be provided.

(2) For using imported hard capsules:

The composition of the hard capsule (name and content) shall be listed in the CTD format 3.2.P.1, and the information of specifications, analytical procedures, validations of analytical procedures (the validation test can be waived if the analytical method followed the pharmacopoeia), certificates of analysis, and BSE/TSE statements regarding excipients of animal origin etc. shall be described in the CTD format 3.2.P.4.